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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,040	04/09/2001	Junying Yuan	00742/057002	8382
21559	7590	03/24/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,040

Applicant(s)

YUAN ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-24 is/are pending in the application.
4a) Of the above claim(s) 4,5,10,11,13,16 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3,6-9,12,14,15 and 18-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 15, 2003 is acknowledged.

1. Initially, it is noted that applicants' remarks that claim 11 does not read on elected species is correct. Therefore, claims 10 and 16-~~17~~ are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, claim 4, 5, 11 and 13 are withdrawn from further consideration as drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

The claims have been examined insofar as they're read on the elected invention and species.

Claim Rejections 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 6-9, 12, 14, 15 and 18-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Klunk et al. (US 6,417,178), in view of Klunk et al. and Huang et al. for reasons set forth in the prior office action.

Response to the Arguments

Applicants' amendments and remarks submitted December 15, 2003 have been fully considered, but are not persuasive for reasons discussed below.

4. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion, or motivation are found both in the prior art, and in the knowledge generally available to one of ordinary skill in the art. Particularly, cited prior arts teaches that Congo red and the Congo red analogues employed in '178 are known to be similarly useful as amyloid binding agents for reducing toxicity, one of ordinary skill in the art would have seen the employment of Congo red for the utility disclosed in '178.

5. Applicants allege that Klunk references teach away from the instant invention because Klunk discloses that it is known Congo red is inferior to Chrysamine G in term of entering blood-brain barrier. For example, Klunk 2 states "Since Congo red is too highly charged to enter the brain in *significant quantities*,..." Congo red, which may not be as efficient as Chrysamine G in term for entering brain, is nevertheless useful an amyloid binding agents, and is able to enter brain. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or no preferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because *it has been described as somewhat inferior to some other product for the same use*." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art

reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have “relatively acceptable dimensional stability” and “some degree of flexibility,” but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant’s argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since “Gurley asserted no discovery beyond what was known in the art.” 27 F.3d at 554, 31 USPQ2d at 1132.). Further, applicants have not provided evidence to the contrary for Congo red’s ability to enter blood brain barrier.

With respect to the remarks about Huang references, note Huang was cited to show two facts: Congo red binding to the amyloid from Huntington diseases; and amyloid from Huntington disease has expanded polyglutamine segment. Nowhere in the detailed disclose negate those facts. Note the obvious rejections is based on the totality of the cited references, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants also contend that the instant invention is directed to the treatment of expanded polyglutamine repeats and not A β diseases. The arguments are not persuasive. Particularly, expanded polyglutamine repeats would read on A β diseases. See, particularly, claims 13 and 14 herein and Huang references.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

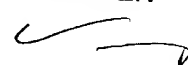
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang 

March 13, 2004